OCT 23 2009 K091152

510(k) Summary

Submitter:	ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439
Contact Person:	Hamid Idrissi Regulatory Affairs Project Manager ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439 Phone: 952-646-3171 Fax: 952-646-3110 idrissih@ARKRAYusa.com
Date Prepared:	October 19, 2009
Trade Name:	GLUCOCARD® Vital™ Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345 and 862.1660; Class II
Product Codes:	CGA, NBW, JJX
Predicate Device:	Ferrara Meter (K063068)
Device Description:	The GLUCOCARD® Vital™ Blood Glucose Monitoring System consist of a meter, test strips, and control solution for use as an aid to monitor the effectiveness of diabetes control.
Intended Use:	The GLUCOCARD® Vital™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. The GLUCOCARD® Vital™ Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.
Functional and Safety Testing:	A full array of in-house and clinical testing was done consistent with relevant FDA guidance's for blood glucose monitoring systems. Bench testing included evaluation of interferences, Dynamic range and linearity, hematocrit effects, altitude effects, control solution functionality, and analytical precision. Clinical testing included evaluation of accuracy for finger stick and palm test sites for GLUCOCARD® Vital™.
Conclusion:	Labeling, bench testing results and clinical testing results support the Indications for Use and the claim of substantial equivalence to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Arkray Factory USA, Inc.
c/o Mr. Hamid Idrissi
Regulatory Affairs Project Manager
5182 W. 76th Street
Minneapolis, MN 55439

OCT 23 2009

Re: k091102
Trade Name: Glucocard® Vital™ Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: September 09, 2009
Received: September 10, 2009

Dear Mr. Idrissi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

1 Indications for Use Statement (GLUCOCARD® Vital™)

510(k) Number (if known):

Device Name: GLUCOCARD® Vital™ Blood Glucose Monitoring System

Indications For Use:

GLUCOCARD® Vital™ Blood Glucose Monitoring System:
The GLUCOCARD® Vital™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.
The GLUCOCARD® Vital™ Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

GLUCOCARD® Vital™ Blood Glucose Meter:
The GLUCOCARD® Vital™ Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD® Vital™ Blood Glucose Test Strips:
GLUCOCARD® Vital™ test strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms when used with the GLUCOCARD® Vital™ Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use in home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Dose CONTROL:
For use with GLUCOCARD® Vital™ Blood Glucose Meter and GLUCOCARD® Vital™ Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Control solutions are available in two levels – Level 1 (Normal) and Level 2 (High).

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) 12a1102